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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,871	08/29/2003	Horace Winston Hale	HORA.P0101US	9347
23908	7590	02/08/2006	EXAMINER	
RENNER OTTO BOISSELLE & SKLAR, LLP			REIMERS, ANNETTE R	
1621 EUCLID AVENUE			ART UNIT	
NINETEENTH FLOOR			PAPER NUMBER	
CLEVELAND, OH 44115			3733	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/651,871

Applicant(s)

HALE ET AL.

Examiner

Annette R. Reimers

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on telephone election of 01/30/06.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
4a) Of the above claim(s) 21-40 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 08/29/03, 11/26/04, 05/31/05
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, drawn to a facet implant, classified in class 623, subclass 17.11.
- II. Claims 21-35, drawn to a method for providing articulating surfaces for facet joint articular facets, classified in class 623, subclass 17.14.
- III. Claims 36-40, drawn to a rasp for preparing an articulating surface of a facet joint articular facet for an implant, classified in class 606, subclass 85.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the method can used for providing articulating surfaces for a different joint, e.g. an intervertebral joint.

Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the method can practiced by a different apparatus, e.g. a curette.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, inventions I and III involve different apparatuses, a facet implant and a rasp, respectively, each of which has a different mode of operation, a different function, and different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above, and the search required for Group I is not required for Group II or Group III, and vice versa, and the search required for Group II is not required for Group III, and vice versa, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark Johnson, applicant's representative, on Monday, January 30, 2006, a provisional election was made without traverse to prosecute Invention I, claims 1-20, with claims 1-20 reading on the elected invention. Examiner agrees with applicant regarding all of the claims reading on elected invention I. Affirmation of this election must be made by applicant in replying to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 21-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the telephone conversation on Monday, January 30, 2006.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject matter of claims 6 and 17, i.e. ridges oriented in a different direction, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of

Art Unit: 3733

the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-11, and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by the Shelokov (US Patent Number 6,039,763).

Shelokov discloses a facet implant comprising a superior implant, 1, having an articulating surface and a fixation surface and configured for placement on a superior articular facet, a inferior implant, 10, having an articulating surface and a fixation surface and configured for placement on an inferior articular facet and for interacting with a translaminal fixation mechanism, wherein the articulating surface of the superior implant and the articulating surface of the inferior implant are configured to interact, and a translaminal fixation mechanism for securing the inferior implant to the inferior articular facet (see figures 1a-1c, 2a-2c, 5a-5d, 7 and column 9, lines 40-46). The superior implant and the inferior implant comprise a surface fixation mechanism, e.g. 6, 7, 16 and 17, such as one or more pegs, one or more pips, ridges, or one or more screws (see figure 1a-1b, 2a-2b column 9, lines 20-39 and column 10, lines 11-14). Furthermore, Shelokov teaches the use of a porous coating, and an implant composed

Art Unit: 3733

of at least one of cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, and Ti/Al/V (see column 9, lines 63-67 and column 10, lines 15-20).

It is noted that the preamble of claim 1 recites "a facet implant" which amounts to an intended use recitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shelokov (US Patent Number 6,039,763).

Shelokov discloses the claimed invention except for the inferior implant being configured to interact with the translaminar fixation mechanism such that the translaminar fixation mechanism ranges from about 0 degrees to about 15 degrees offset and the superior and inferior implants ranging from about 2 mm thick to about 15 mm thick. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Shelokov with the inferior implant being configured to interact with the translaminar fixation mechanism such that the translaminar fixation mechanism ranges from about 0 degrees to about 15 degrees

Art Unit: 3733

offset and the superior and inferior implants ranging from about 2 mm thick to about 15 mm thick, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER